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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/017,743	02/03/98	SETTE	A 018623-00805

HM22/0508

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EXAMINER	
DIBRINO, M	
ART UNIT	**PAPER NUMBER**
1644	16

DATE MAILED: 05/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/017,743	Sette et al
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 8-70 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 8-70 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☑ Notice to Comply with Sequence Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.
The paper copy of the Sequence Listing has 146 SEQ ID NOS, whereas the CRF has only 140.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 8-10, 17-27, 28-30, 36-46 and 66-70, drawn to an isolated nucleic acid encoding a peptide and a pharmaceutical composition, thereof, classified in Class 536, subclass 23.5.

II. Claims 11-16, 31-35 and 47-65, drawn to an isolated nucleic acid encoding a peptide polymer, classified in Class 536, subclasses 23.1 and 23.72.

3. Inventions I and II are different products.

A nucleic acid encoding a peptide is different from another encoding a homo-or hetero-polymer because they have different sequences, structures and physico-chemical properties.

Therefore they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II and Groups I and II have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed Invention: compound and composition, thereof, wherein the nucleic acid encodes a peptide sequence that is one of the peptides disclosed in the specification and is encompassed by the elected motif amino acid at the elected motif position. Applicant is required to elect a nucleic acid encoding a specific species of peptide and motif (from P at Position 2 and one of V, I, L, F, M, W, Y, A at the carboxy terminal position), for example, SEQ ID NO: 4 and the motif P at Position 2 and L at the carboxy terminal position .

The nucleic acids encoding these peptides are functionally and structurally distinct, as are the peptides themselves.

6. In addition, this application contains claims directed to the following patentably distinct species of the claimed invention:

A) a peptide of 8 amino acid residues
B) a peptide of 9 amino acid residues
C) a peptide of 10 amino acid residues

D) a peptide of 11 amino acid residues

These peptides are distinct because they have different lengths and hence, different structures and different physico-chemical properties.

Applicant is required to elect a specific species of peptide having a specific length, i.e., one of A-D above.

7. Applicant is further required to elect one ultimately disclosed species of an antigen of interest which is:

A) a cancer-associated antigen **or**
B) a pathogenic agent.

If a cancer-associated antigen is elected, Applicant is further required to elect one of the patentably distinct species of cancer antigen disclosed, for example MAGE 2, p53, HER2/neu, CEA or prostate.

If a pathogenic agent is elected, Applicant is further required to elect one of the patentably distinct species disclosed, for example, HBV, HCV, HIV or malaria.

These species are distinct because they have different structures and physico-chemical properties and cause different diseases.

8. Applicant is further required to elect a single disclosed species of a specific HLA molecule, i.e., a specific HLA molecule recited in claim 17, 36 or 55, such as for example, HLA-B0701.

These species are distinct because different HLA molecules have different functional and structural properties.

9. Applicant is further required to elect a single disclosed species of peptide having an IC_{50} of less than about 500 nM or of less than about 50 nM for an HLA molecule.

These species are distinct because they are different peptides having different functional and structural properties.

10. If the Invention of Group II is elected, Applicant is further required to elect a single disclosed species of "additional peptide" wherein the additional peptide is a T helper epitope or a CTL epitope.

These species are distinct because they are different peptides having different functional and structural properties.

Therefore, they are patentably distinct.

11. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640/ Technology Center 1600
May 4, 2000

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1640